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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

LELIA INES BESSONE DE CASTRO,
individually, and as Personal
Representative of and as Successor in
Interest to the Estate of the Decedent
FABIAN ADOLFO CASTRO,

Plaintiff,

v.

ALPHA THERAPEUTIC
CORPORATION, A California
corporation, BAYER CORPORATION, an
Indiana Corporation; BAXTER
HEALTHCARE CORPORATION, a
Delaware corporation, and its HYLAND
DIVISION; ARMOUR
PHARMACEUTICAL COMPANY, INC.,
a Delaware corporation, and AVENTIS
INC., a Pennsylvania corporation,

Defendants.

Case No. 07-4418

**COMPLAINT FOR DAMAGES AND
INJUNCTIVE RELIEF:**

(1) NEGLIGENCE
(SURVIVAL ACTION)

MEJ

(2) NEGLIGENCE PER SE
(SURVIVAL ACTION)

(3) FRAUDULENT OMISSION AND
CONCEALMENT
(SURVIVAL ACTION)

(4) BREACH OF IMPLIED WARRANTY
(SURVIVAL ACTION)

(5) WRONGFUL DEATH

DEMAND FOR JURY TRIAL

I. INTRODUCTION

1. Plaintiff's claims arise out of the most egregious misconduct in the history of the pharmaceutical industry, which resulted in the killing of thousands of hemophiliacs worldwide, with a continuing death rate of hundreds of victims per year. Defendants are

1 American corporations which manufactured blood products known as "Factor VIII" and
2 "Factor IX" for the treatment of hemophilia, and sold these products to hemophiliacs worldwide,
3 despite knowledge that the products were manufactured from sick, high risk donors and/or known
4 to be contaminated with the viruses that cause AIDS and Hepatitis C (now known as HIV and
5 HCV respectively). Defendants continued selling these products to hemophiliacs abroad even
6 after the products were no longer being used in the United States due to the known risk of AIDS
7 and Hepatitis C transmission, and continued selling old stocks of products they knew to be
8 contaminated with HCV both in the United States and abroad even after they had introduced a
9 safer product. Decedent Fabian Adolfo Castro was a hemophiliac who contracted HIV and
10 Hepatitis C through use of Defendants' contaminated products.

11 2. Defendants manufactured HIV and HCV-contaminated blood factor
12 products at plants in the United States using human plasma taken from thousands of paid
13 American donors, including populations then known to be at high risk of carrying blood-borne
14 diseases, such as urban homosexuals, prisoners, and intravenous drug users. Defendants
15 intentionally recruited urban homosexuals who had a history of viral hepatitis as plasma donors,
16 despite regulations prohibiting the use of such donors and despite knowledge that the viruses that
17 cause AIDS and Hepatitis C were blood-borne diseases prevalent in such populations.
18 Defendants continued using plasma taken from high risk prison donors, including from prisoners
19 at the notorious Angola prison in Louisiana, even after promising the FDA that they would cease
20 doing so. Through their trade associations, Defendants actively conspired to conceal these
21 practices and to substantially delay product recalls and implementation of safety measures.

22 3. Defendants failed to fully and completely disclose the known risks of their
23 products, including the risk of AIDS and Hepatitis C; failed to implement readily available
24 screening tests that would have prevented AIDS and Hepatitis C by excluding contaminated
25 plasma; failed to use available methods of treating plasma to kill viruses, including heat treatment
26 and solvent detergent; and concealed and affirmatively misrepresented the extent of the health
27 dangers of the diseases caused by the products. Defendants continued to ship non-heat treated
28 product overseas even after ceasing to sell it in the United States, in order to maintain their profit

1 margin on existing contracts and sell off remaining stock no longer marketable domestically.
2 Defendants also continued to sell old stocks of product that had not been treated with detergent
3 both in the United States and abroad, even after introducing a safer product treated with detergent.

4 4. Defendants' efforts to maximize profits came at the expense of the health
5 and lives of thousands of hemophiliacs worldwide who were needlessly infected with HIV and/or
6 HCV. AIDS is the leading cause of death for hemophiliacs who were treated with factor
7 concentrate in the 1980's, and the average life expectancy of hemophiliacs has decreased
8 substantially. As of 1992, Defendants' contaminated blood products had infected at least 5,000
9 European hemophiliacs with HIV, of which 2,040 had already developed AIDS and 1,250 had
10 died from the disease. In the United Kingdom, 34% of hemophiliacs tested positive for HIV in
11 1992. As of the mid-1990's in Japan, hemophiliacs accounted for the majority of Japan's 4,000
12 reported cases of HIV infection, and virtually all infections of Japanese hemophiliacs have been
13 linked to contaminated blood products imported from the United States. In Hong Kong and
14 Taiwan, over one hundred hemophiliacs were infected with HIV by Defendant CUTTER's
15 products alone. In Latin America, at least 700 HIV cases are linked to use of contaminated blood
16 products by hemophiliacs. Thousands more around the world were infected with Hepatitis C
17 from Defendants' products.

18 **II. JURISDICTION AND VENUE**

19 5. Plaintiff alleges an amount in controversy in excess of \$75,000, exclusive
20 of interest and costs. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332
21 because there is complete diversity of citizenship between the Plaintiff and the Defendants.

22 6. Plaintiff is informed and believes and upon such information and belief
23 alleges that the unlawful, negligent and/or tortious activity alleged herein was carried out
24 predominantly in the United States. Defendants recruited high risk paid donors in the United
25 States and mixed plasma from such donors into the blood pool at their facilities in the United
26 States. Defendants placed misleading labels on their products in the United States and made
27 affirmative misrepresentations regarding their products' safety in the United States, which were
28 relied upon by Decedent and his doctors worldwide. Defendants' decisions to recruit paid donors

1 from high risk populations, to refrain from disclosing the known risks of their products, to forego
2 implementing readily available procedures that would have prevented their products from
3 transmitting AIDS, and to ship their products overseas even after they could no longer be used
4 domestically were all made in the United States. Defendants' acts of conspiracy, including trade
5 association meetings where they agreed to engage in wrongful conduct, also took place in the
6 United States.

7 7. Plaintiff is informed and believes and upon such information and belief
8 alleges that the vast majority of the evidence of the unlawful activity alleged herein is located in
9 the United States. Documents showing Defendants' policies, practices, and decisions regarding
10 recruitment of plasma donors, mixing of plasma into the blood pool at their facilities, labeling of
11 their products, advertising and promotion of their products, disclosure or lack thereof of the risks
12 posed by their products, implementation or lack thereof of procedures to prevent their products
13 from transmitting AIDS, and shipment of their products overseas are located almost exclusively
14 in the United States. The vast majority of witnesses who will testify to these policies, practices,
15 and decisions are also located in the United States, and would not be subject to subpoena in other
16 countries. The expert witnesses likely to be presented by both Plaintiff and Defendants are also
17 located in the United States.

18 8. Decedent Castro's available medical records have already been brought to
19 the United States and are being translated into English. In addition, witnesses to the Plaintiff's
20 and Decedent's damages and family members of the Plaintiff and Decedent are willing to travel
21 to the United States to testify.

22 9. Plaintiff is informed and believes and upon such information and belief
23 alleges that Defendants' unlawful activity was carried out, in significant part, in the Central
24 District of California. Defendant BAXTER CORPORATION, and/or its HYLAND DIVISION,
25 had its main manufacturing plant in Glendale, California, in the Central District. HYLAND's
26 President, Medical Director, and Head of Donor Recruitment all had their offices in the Glendale
27 facility. Defendant BAXTER, and/or its HYLAND DIVISION, also recruited all their
28 homosexual donors from California, particularly from San Francisco and Los Angeles. All

1 Defendants obtained plasma from plasma collection centers located in San Francisco and
2 Oakland, California.

3 10. Plaintiff is informed and believes and upon such information and belief
4 alleges that the evidence of Defendants' unlawful activity is located, in significant part, in the
5 Central District of California, where much of the unlawful activity was carried out.

6 **III. PARTIES**

7 11. Decedent Fabian Adolfo Castro was a citizen and resident of Argentina and
8 a hemophiliac who used Defendants' factor concentrate and was infected with HIV and
9 Hepatitis C as a direct and proximate result thereof, and contracted AIDS as a further result of his
10 exposure to Defendants' factor concentrate and/or as a result of Defendants' conspiracy. His
11 death was a direct and proximate result of his exposure to Defendants' factor concentrate.

12 12. Plaintiff Lelia Ines Bessone de Castro was the Decedent's mother, and is
13 the Personal Representative of and Successor in Interest to the Estate of the Decedent Fabian
14 Adolfo Castro. She is also a resident and citizen of Argentina. She has incurred time and
15 expenses caring for her ill son, has suffered loss of support and has suffered other damages as a
16 result of her son's factor concentrate induced viral infections and illnesses..

17 13. Decedent Castro would not have chosen to have been treated with
18 Defendants' blood products had he known of or been informed by Defendants of the true risks of
19 using those products or the nature of the sources of the blood products.

20 14. Defendant CUTTER, the predecessor of Miles, Inc., and Defendant
21 BAYER, was a California corporation headquartered in Berkeley, California at all pertinent
22 times. At all pertinent times CUTTER and its successors Miles, Inc. and BAYER regularly and
23 systematically engaged in the harvesting and collection of human plasma and the processing,
24 manufacturing, marketing, sales and distribution of anti-hemophilic factor (hereinafter referred to
25 as "AHF") produced from such plasma, to which Decedent was exposed and which contributed
26 directly or indirectly to Decedent's infection with HIV and/or HCV.

27 15. Defendant BAYER, formerly Miles, Inc., is and was an Indiana
28 corporation, authorized to do business in all 50 states and the District of Columbia. Miles, Inc.

1 had its principal place of business operation in Elkhart, Indiana, while its successor BAYER has
2 its principal place of business in Pennsylvania, with offices located at 100 Bayer Road,
3 Pittsburgh, Pennsylvania 15205. At all pertinent times BAYER and its predecessors Miles, Inc.,
4 and CUTTER regularly and systematically engaged in the harvesting and collection of human
5 plasma and the processing, manufacturing, marketing, sales and distribution of anti-hemophilic
6 factor (hereinafter referred to as "AHF") produced from such plasma, to which Decedent was
7 exposed and which contributed directly or indirectly to Decedent's infection with HIV and/or
8 HCV.

9 16. Defendant BAXTER HEALTHCARE CORPORATION (hereinafter
10 "BAXTER") is a Delaware corporation, authorized to do business in all 50 states and the District
11 of Columbia, with its principal place of business in Illinois, with offices located at One Baxter
12 Parkway, Deerfield, Illinois 60015. At all times pertinent, Defendant BAXTER, and/or its
13 HYLAND DIVISION, had its main manufacturing plant in Glendale, California. In 1997,
14 BAXTER acquired all assets and liabilities of Immuno International A.G., an Austrian company
15 that at all times pertinent sold AHF products worldwide which were produced from human
16 plasma derived from paid donors in the United States. Immuno International A.G. operated in the
17 United States at all times pertinent through its wholly owned American subsidiary Immuno-U.S.,
18 located in Rochester, New York. At all times pertinent, Defendant BAXTER, and/or its
19 HYLAND DIVISION, and/or its wholly owned subsidiaries Travenol Laboratories and Fenwal
20 Laboratories, regularly and systematically engaged in the harvesting and collection of human
21 plasma and the processing, manufacturing, marketing, sales and distribution of AHF products
22 produced from such plasma, to which Decedent was exposed and which contributed directly or
23 indirectly to Decedent's infection with HIV and/or HCV.

24 17. Defendant ARMOUR PHARMACEUTICAL COMPANY, INC. is a
25 Delaware corporation, authorized to do business in all 50 states and the District of Columbia, with
26 its principal place of business in Pennsylvania, with offices located at 500 Arcola Road, P.O.
27 Box 1200, Collegeville, Pennsylvania 19426-0107. In 1996 Defendant ARMOUR merged with
28 Behringwerke A.G., a German company that at all times pertinent sold AHF products which were

1 produced from human plasma derived from paid donors in the United States, to form Defendant
2 AVENTIS BEHRING LLC, formerly Centeon Bio-Services, Inc., a Delaware company with
3 offices located at 1020 First Avenue, King of Prussia, Pennsylvania 19406. Defendant AVENTIS
4 BEHRING LLC and its predecessors, Centeon Bio-Services, Inc. and Armour Plasma Alliance,
5 Inc., are wholly owned subsidiaries of Defendant AVENTIS INC., formerly Rhone-Poulenc
6 Rorer International, Inc., formerly Rorer Group, Inc., a Pennsylvania corporation authorized to do
7 business in all 50 states and the District of Columbia, with offices located at 300 Somerset
8 Corporate Boulevard, Bridgewater, New Jersey 08807. At all times pertinent, Defendants
9 ARMOUR PHARMACEUTICAL COMPANY, INC., AVENTIS BEHRING LLC, and
10 AVENTIS INC. (all of whom are described hereinafter collectively as "ARMOUR"), regularly
11 and systematically engaged in the harvesting and collection of human plasma and the processing,
12 manufacturing, marketing, sales and distribution of AHF products produced from such plasma, to
13 which Decedent was exposed and which contributed directly or indirectly to Decedent's infection
14 with HIV and/or HCV.

15 18. Defendant ALPHA THERAPEUTIC CORPORATION (hereinafter
16 "ALPHA") is a California corporation authorized to do business in all 50 states and the District of
17 Columbia, with its principal place of business in California, with offices at 5555 Valley
18 Boulevard, Los Angeles, California 90032. ALPHA is a wholly owned subsidiary of The Green
19 Cross Corporation (hereinafter "Green Cross"), a Japanese business corporation. At all times
20 pertinent Defendant ALPHA and its parent, Green Cross, have been regularly and systematically
21 engaged in the harvesting and collection of human plasma and the processing, manufacturing,
22 marketing, sales and distribution of AHF products produced from such plasma, to which
23 Decedent was exposed and which contributed directly or indirectly to Decedent's infection with
24 HIV and/or HCV.

25 19. Defendants CUTTER, ARMOUR, BAXTER and ALPHA (hereinafter
26 collectively referred to as "MANUFACTURERS") acting on behalf of themselves and/or their
27 predecessor and/or successor corporations, collected, harvested and/or processed human plasma
28 and/or manufactured, marketed, sold and distributed AHF products worldwide that were

1 contaminated with HIV and/or HCV. In the alternative, one or more of said Defendants
2 participated in the collection, harvesting and/or processing of human plasma and/or the
3 manufacturing, marketing, distribution and sale of AHF products worldwide, or assumed, became
4 or are responsible for the liabilities of the Defendants and their predecessor or successor
5 corporations who did participate in the collection, harvesting and/or processing of human plasma
6 and/or the manufacturing, marketing, distribution or sale of AHF products worldwide, without
7 limitation thereto.

8 20. At all times herein mentioned, all Defendants and each of them, were fully
9 informed of the actions of their agents and employees, and thereafter no officer, director or
10 managing agent of Defendants repudiated those actions, which failure to repudiate constituted
11 adoption and approval of said actions and that all Defendants and each of them, thereby ratified
12 those actions.

13 **IV. FACTUAL ALLEGATIONS APPLICABLE TO ALL CLAIMS**

14 **A. Hemophilia and Its Treatment**

15 21. Hemophilia is an inherited condition that causes uncontrolled
16 hemorrhaging or bleeding. Hemophilia results from a deficiency of blood components essential
17 for coagulation. The most common form of the disease is hemophilia A, characterized by a lack
18 of a blood protein known as Factor VIII, which affects approximately one in 10,000 males.
19 Factor VIII is commonly called "AHF," or antihemophilic factor. Hemophilia B is characterized
20 by absence of another blood protein, known as Factor IX, affecting about one in 40,000 males.
21 Von Willebrand's disease is an inherited hemorrhagic condition similar to hemophilia that affects
22 both men and women. It is characterized by lack of both Factor VIII and another blood protein
23 called von Willebrand's factor.

24 22. The treatment of hemophilia and von Willebrand's disease involves
25 intravenous introduction, called infusion, of the missing blood proteins required to stop bleeding.
26 The two most prevalent forms of such treatment are cryoprecipitate, and factor concentrates.
27 Factor concentrates are the product made by Defendants in this action. Cryoprecipitate is made
28 by freezing plasma, the fluid component of circulating blood in which various proteins, including

Factor VIII and Factor IX, are contained; thawing the frozen plasma; and isolating Factor VIII from the plasma through centrifugal concentration. Cryoprecipitate is an effective therapeutic agent for patients with hemophilia A. Hemophilia B has been effectively treated with the use of fresh frozen plasma containing Factor IX. Cryoprecipitate and fresh frozen plasma are made from small numbers of donors, who are generally unpaid volunteers.

23. By contrast, Defendants in the late 1960s to early 1970s began to market factor concentrates, or AHF, which contained Factor VIII and Factor IX in higher concentrations than had been available in either cryoprecipitate or fresh-frozen plasma. To produce factor concentrates, Defendants mixed pools of plasma from five to twenty thousand donors at a time, a substantial percentage of which were paid donors. These large pools were then subjected to chemical process to concentrate Factors VIII and IX.

B. Even Before the Discovery of HIV and AIDS, Defendants Failed to Disclose or Warn of Serious Adverse Effects Associated with Factor Concentrates

24. Shortly after the initial commercial marketing of Factor VIII and IX concentrates in the late 1960s to early 1970s, a wide range of serious adverse effects were reported in association with these products. Even before the dissemination of HIV, Defendants knew of serious diseases caused by unidentified agents transmissible by blood and Factor VIII and IX. Defendants failed to warn Plaintiff or Decedent or the medical community of these adverse effects, in violation of industry standards and federal regulations.

25. By 1976, only a few years after Defendants' factor concentrate products went on the market, the United States Food and Drug Administration ("FDA") Bureau of Biologics held a conference entitled "Unsolved Therapeutic Problems in Hemophilia." The research articles compiled from the conference discussed the high incidence in patients using Defendants' products of disorders such as liver dysfunction, enlarged spleen, Hepatitis B, and Non-A, Non-B Hepatitis ("NANB Hepatitis," later renamed Hepatitis C). The articles concluded that these disorders were tied to the patients' use of factor concentrates, and emphasized the risks entailed in producing such concentrates using plasma from paid donors. For instance, Robert Gerety of the FDA Bureau of Biologics, Division of Blood and Blood Products, reported that the

1 agent or agents of NANB Hepatitis “appear to be blood borne, perhaps to be associated with a
2 form of chronic hepatitis, and to represent a considerable risk to recipients who repeatedly require
3 the administration of blood products.” (Gerety, et al., “Viral Antigens and Antibodies in
4 Hemophiliacs,” (1977)). Gerety noted that “[t]he use of large plasma pools from paid donors no
5 doubt contributes to the risk of HBV [Hepatitis B] infection from these products,” and stated that
6 “an all voluntary blood donor system is being pursued as a result of the known increased risk of
7 PTH [post-transfusion hepatitis] from blood derived from commercial donors.” As described
8 below, however, Defendants not only refused to implement such a voluntary donor system, but
9 instead recruited paid donors precisely because their hepatitis exposure resulted in plasma from
10 which Defendants could make other commercially valuable products as well.

11 26. Several of the articles from the 1976 conference also raised alarm over the
12 unprecedented convergence of immune disorders in the hemophiliac community, and called for
13 close medical monitoring of the situation. Dr. Peter Levine stated, “one wonders whether our
14 patients are suffering a sort of immune complex disease as a result of intensive bombardment
15 with foreign antigens....” (Levine, “Unsolved Problems with Current Therapeutic Regimens for
16 Hemophilia,” (1977)). Shapiro warned of the possibility that “a new spectrum of disease may be
17 seen in this population” and urged that it “behooves us to follow the suggested findings very
18 closely over the coming years.” (Shapiro, “Antibody Responses in the Hemophiliac,” (1977)).
19 Seeff concurred that “it is evident that continued surveillance of the hemophiliac population is
20 mandatory.” (Seeff, “Acute and Chronic Liver Disease in Hemophilia,” (1977)).

21 27. At all times material to this Complaint, Defendants failed to adequately
22 warn Plaintiff or the Decedent or his physicians of these serious adverse side effects. Several such
23 adverse effects, including immunosuppression (suppression of the immune system) were not
24 mentioned at all in the Defendants’ package inserts, which were required to disclose adverse
25 reactions pursuant to federal statutes and regulations and applicable standards of care. Although
26 Defendants’ inserts mentioned a risk that plasma “may” contain the causative agent of viral
27 hepatitis, the warning was seriously deficient in that: (a) Defendants failed to disclose that the
28 risk of hepatitis was essentially a 100% guarantee due to their practices of using high-risk donors

1 and specifically recruiting for donors who had previously been exposed to Hepatitis B; (b) while
 2 “hepatitis” simply means inflammation of the liver, and may be a relatively benign, temporary
 3 condition, Defendants failed to warn that some forms of hepatitis transmitted by their products
 4 were believed to present a considerable risk of severe liver damage, cirrhosis, and significantly
 5 elevated risk of cancer; (c) Defendants misleadingly stated that the source plasma used in
 6 preparation of the product had been found to be non-reactive for Hepatitis B surface antigen
 7 (HBsAg)-implying that no viral hepatitis was present in the plasma-and falsely stated that
 8 available methods were not sensitive enough to detect all units of potentially infectious plasma,
 9 while failing to disclose that Defendants had refused to implement the more sophisticated
 10 Hepatitis B Core Antibody (HBc) test which would have excluded essentially all plasma
 11 contaminated by Hepatitis B; and (d) Defendants’ labeling disclosed that the product was made
 12 from large pools of fresh human plasma, but failed to disclose that paid donors increased the risk
 13 of disease, and that the particular groups of paid donors targeted by Defendants were known to be
 14 the highest risk groups available.

15 C. **Defendants Recruited Plasma Donors from High Risk Populations to**
 16 **Manufacture Factor VIII and IX**

17 28. The demand for and supply of anti-hemophilia factor rapidly increased
 18 during the 1970’s, with the commercially-manufactured concentrate accounting for a large
 19 proportion of the increase in supply. In 1977, a federal report projected that the volume of AHF
 20 manufactured would increase substantially by 1980. (“Study to Evaluate the Supply-Demand
 21 Relationships for AHF and PTC Through 1980,” Division of Blood Diseases and Resources,
 22 National Heart, Lung and Blood Institute (1977), at page 8; hereinafter “NHLBI Report”).

23 29. In order to sell more AHF to this growing market, Defendants turned to the
 24 fastest and cheapest way of obtaining sufficient plasma, paid donors. Defendants recruited paid
 25 donors from those populations most likely to respond to the financial incentive to donate: poor
 26 inner city residents, drug abusers, prisoners, and even residents of impoverished developing
 27 countries such as Haiti and Nicaragua.

28 30. Defendants purposefully sought out paid donors despite knowing that the

1 risk of diseases transmissible by blood was far greater among paid donors than among volunteers.
2 Because no test was available yet for the NANB Hepatitis virus identified in the early 1970's, the
3 only means to prevent the virus from contaminating the plasma supply was to exclude donors
4 with behaviors that were inconsistent with good health-precisely those populations from which
5 Defendants were recruiting paid donors. Some studies indicated that paid donors were up to ten
6 times more infectious than volunteer donors. For this reason, the National Blood Policy, adopted
7 by the federal government in July 1973, advocated conversion to an all-volunteer blood supply.
8 Defendants, however, not only continued to use paid donors, but also focused their recruiting
9 efforts on the highest risk populations.

10 31. Defendants had an additional financial incentive for recruiting paid donors.
11 Factor VIII and Factor IX are only two of many products that can be made for commercial sale
12 from human plasma. According to the NHLBI Report, by the late 1970s at least 17 different
13 therapeutic components of blood were manufactured by the process of "fractionating" plasma into
14 its various elements. The NHLBI Report noted that, "as the costs of fractionation have increased,
15 fractionators have produced as many products as possible from a liter of plasma." (Id. at 65).

16 32. Blood derivatives used as vaccines or therapeutics had particularly high
17 economic value for Defendants. The NHLBI Report noted that plasma with a very high titer, or
18 antibody level, for a corresponding antigen is "very expensive." (Id. at 41). Such products are
19 manufactured from source plasma drawn from donors who have been sensitized to a particular
20 antigen. (Id.). The NHLBI Report specifically stated, however, that "plasma collected for high
21 antibody titer cannot be used for fractionation into therapeutic products," such as Defendants'
22 factor concentrate. (Id., emphasis added).

23 33. Defendants targeted donors with high titers to Hepatitis B antigens in order
24 to manufacture and sell Hepatitis B immunoglobulin (HBIG), a product that confers temporary
25 immunity to the Hepatitis B virus. Despite the warning in the NHLBI report, Defendants used the
26 same high titer plasma they obtained for making HBIG to manufacture the Factor VIII and IX
27 products used by hemophiliacs. Defendants thus sought to maximize profits by producing "as
28 many products as possible from a liter of plasma," while ignoring industry standards that

1 precluded the use of high-titer plasma for other therapeutic products.

2 34. Beginning in about 1978, Defendants BAXTER, CUTTER and ALPHA
3 began targeting homosexual donors in known urban gay communities. Because urban
4 homosexuals had been reported in the 1970's to have exceptionally high prevalence of
5 Hepatitis B infection, Defendants knew that such donors would provide a reliable source of
6 plasma for the manufacture of commercially valuable HBIG.

7 35. It was also well-known in the public health community by the 1970's that
8 urban homosexuals engaged in promiscuous sexual practices that rapidly transmitted other
9 diseases, including NANB Hepatitis, which were transmitted by blood, could not be isolated nor
10 identified, and were believed to have serious adverse consequences. Despite this knowledge,
11 Defendants used the same plasma pool from urban homosexuals to manufacture both HBIG and
12 Factor VIII and IX.

13 36. Defendants continued this dual use of high risk plasma even after federal
14 reports warned of the rapid spread of fatal immunosuppressive disease among the same
15 homosexual population from which Defendants heavily recruited. On June 5, 1981, the United
16 States Centers for Disease Control ("CDC") reported that five homosexual men had unusual and
17 similar immunosuppressive disorders (Morbidity and Mortality Weekly Report, hereinafter
18 "MMWR," June 5, 1981, at p. 250). On July 3, 1981, the CDC reported similar diseases in 26
19 homosexuals, noting that all 12 patients tested for cytomegalovirus ("CMV") had evidence of
20 "past or present CMV infection," and that past infections with hepatitis "were commonly
21 reported." (MMWR, July 3, 1981, at p. 305). The CDC warned doctors to be alert for
22 "opportunistic infections associated with immunosuppression in homosexual men." (Id., at
23 p. 307). By August 28, 1981, less than two months later, the reported figure had grown to 108
24 cases and 40% fatalities; 94% of the 101 males were homosexual or bisexual (MMWR,
25 August 28, 1981, at p. 409). Based on this evidence and the high prevalence of hepatitis in the
26 same population, Defendants knew or should have known by no later than the summer of 1981
27 that urban homosexual males were not "suitable donors" within the meaning of federal
28 regulations and/or other applicable standards of care.

1 37. By the 1970s, it was also well-established that plasma from prison
2 populations carried a high risk of hepatitis and other blood-borne diseases, primarily because of
3 the concentration of intravenous (IV) drug users in prisons. By 1974, the alanine
4 aminotransferase ("ALT") test was available to test for elevated levels of liver enzymes called
5 SGOT that indicate the presence of hepatitis. Prisoners were associated with SGOT levels of
6 over 60 Ns per ml, a level that increases the risk of Hepatitis C transmission by a factor of 6.
7 Despite knowledge of this risk, Defendants actively recruited prisoners for plasma used to
8 manufacture Factor VIII and IX, while concealing or failing to disclose the risk to Plaintiff or the
9 Decedent, his physicians, or the FDA.

10 38. On June 11, 1982, the CDC reported that 281 homosexual men and 33 IV
11 drug users had been diagnosed with similar immunosuppression and opportunistic infections,
12 with a 43% fatality rate. Yet Defendants continued to recruit these high risk donors while
13 concealing the risk from Plaintiff, Decedent, his physicians and the FDA. It is highly significant
14 that only Defendants had knowledge of this risk; while the spread of disease in homosexuals and
15 IV drug users became known to the FDA and the public, only Defendants knew that these very
16 populations were target donors for plasma used to make Factors VIII and IX.

17 39. At a July, 1982 meeting attended by Defendants, the CDC publicly
18 reported the first three cases of opportunistic infections among individuals with hemophilia. All
19 three were reported to be heterosexual males. The CDC reported that the clinical and
20 immunologic features of the three patients were strikingly similar to those recently observed
21 among homosexual males and heterosexual IV drug users, while noting that the hemophilia
22 patients did not share the latter two groups' risk factors. The CDC stated, "Although the cause of
23 the severe immune dysfunction is unknown, the occurrence among the three hemophiliac cases
24 suggests the possible transmission of an agent through blood products." (MMWR, July 16, 1982,
25 at p. 366).

26 40. In light of Defendants' special knowledge of the disease patterns among
27 urban homosexuals and prisoners, and their recruitment of such donors for Factor VIII and IX
28 manufacture, Defendants had duties to: (a) promptly investigate the first reports of opportunistic

infections among urban homosexuals in 1981; (b) discontinue the practice of using such high risk donors; (c) disclose the risk to Decedent, his physicians, and the FDA, including the ongoing risk of continuing to use Factor VIII and IX previously manufactured with high risk plasma and still marketed to patients; (d) implement procedures to kill blood-borne diseases in the products; and (e) recall existing products from distribution or further use. Instead, Defendants continued to conceal their recruitment of high risk donors and resist warnings and recalls, and failed to implement procedures to make their products safe.

D. Defendants Failed to Use the Available Hepatitis B Core (HBc) Test to Exclude Plasma from High Risk Donors

41. By no later than 1978, Defendants knew of the availability of a new test to determine whether an individual had a history of viral Hepatitis, which would have disqualified the donor from providing plasma for the manufacture of Factor VIII or IX. By testing a person's serum for the presence of the core to the Hepatitis B antibody, a history of viral Hepatitis could be verified. This was known as the "HBc test." Published, peer-reviewed literature shows that the HBc test was in use by researchers to determine that homosexual AIDS victims had a history of viral Hepatitis by no later than December 1981. (Gottlieb, et al., "Pneumocystis Carinii Pneumonia and Mucosal Candidiasis in Previously Healthy Homosexual Men," NEW ENGLAND JOURNAL OF MEDICINE 1981; 305:1425-1431).

42. Use of the HBc test would have eliminated approximately 75% of homosexual plasma donors and over 90% of promiscuous urban homosexuals. It would have eliminated almost 100% of intravenous drug users.

43. Use of the HBc and ALT tests by Defendants by 1981 would have eliminated the vast majority of the transmitters of HIV and HCV from the blood and plasma pools of the nation, before the height of the AIDS and Hepatitis C epidemics. If Defendants had implemented this test in a timely manner, Decedent would never have been infected with HIV or HCV or suffered from AIDS or Hepatitis C as a result of factor concentrate use.

44. Decedent Fabian Adolfo Castro and thousands of other hemophiliacs worldwide became infected by the AIDS and Hepatitis C viruses through repeated exposures

1 from blood products manufactured from large pools of plasma donors (5,000 to 40,000). If
2 Defendants had used the HBc and ALT tests to decrease by 70% to 90% the number of HIV and
3 HCV positive donors who went into a pool, the infectivity of the product would have decreased
4 substantially. Consequently, the rate of infection of hemophiliacs would have slowed down
5 enormously, and the medical and scientific community would have been given more time to react
6 appropriately to the HIV and Hepatitis C epidemics.

7 45. As noted below, federal regulations required plasma donors to be in good
8 health, and donors with a "history of viral Hepatitis" were by definition unacceptable as blood or
9 blood plasma donors. Persons with a history of viral hepatitis were excluded not only because of
10 the risk of transmitting Hepatitis B, but because such a history indicated a lifestyle or previous
11 behavior of the prospective donor which carried the risk of transmitting other viruses in addition
12 to hepatitis. A reasonable and prudent plasma fractionator would not accept a HBc positive donor
13 and expect to be in compliance with federal regulations as of 1978.

14 46. After public reports of the first hemophilia AIDS cases in July 1982,
15 government officials urged Defendants to implement the HBc test as a "surrogate" or "marker" to
16 eliminate plasma contaminated by the transmitter of AIDS or Hepatitis C. HBc testing was also
17 strongly suggested to Defendants by the CDC at a meeting of the United States Public Health
18 Service ("PHS") on January 4, 1983. Despite this urging, Defendants continued to use
19 contaminated plasma donations that would have been excluded by the HBc test and continued to
20 conceal from Decedent, his physicians, and the FDA the dangerous practice of targeting donors at
21 highest risk for the very diseases that disqualified their plasma. At a January 6, 1983 meeting of
22 Defendants' trade association, the Pharmaceutical Manufacturer's Association, Defendants
23 agreed not to implement the highly effective HBc donor screening, and instead opted to use
24 ineffective donor questionnaires that did little to screen out donors at high risk for AIDS and
25 Hepatitis C transmission.

26 47. As late as December 13, 1983, years after the HBc test was available, a
27 memorandum from CUTTER's responsible head Stephen Ojala to various CUTTER executives,
28 reporting back on a meeting held by all Defendants, shows that all Defendants conspired to

1 propose a "task force" to further study the use of HBc as an intentional, bad faith "delaying tactic
2 for the implementation" of the test.

3 **E. Defendants Also Failed to Implement Available Heat Treatment and Solvent**
4 **Detergent to Kill Blood Borne Diseases**

5 48. In the late 1970s and early 1980s, it was recognized that viruses were in all
6 AHF products, including Factor VIII and IX. Heat treatment and solvent detergent was available
7 at that time to eliminate many of these viruses, including HIV and HCV. Defendants were
8 required to take reasonable steps to eliminate contamination, but Defendants failed to utilize these
9 available technologies to eliminate the viruses in a timely manner.

10 49. The 1977 NHLBI Report noted that albumin, another plasma product, was
11 "heat treated to remove almost all danger of hepatitis." (Id., at p. 49). Defendant ARMOUR'S
12 memorandum of June 1983 acknowledged that no cases of AIDS had been reported in heat-
13 treated albumin users, but misleadingly states that heat treatment of Factor VIII and IX was not
14 yet feasible. It was clearly known by no later than 1977 that heat treatment was an effective way
15 to make blood products safer, but Defendants wrongfully refused to implement such procedures
16 as to Factor VIII and IX. In 1995, the National Institutes of Health Institute of Medicine ("IOM")
17 issued a report on the hemophilia AIDS epidemic which concluded that defendants "did not
18 seriously consider alternative inactivation processes," including heat treatment, and that "heat
19 treatment processes to prevent the transmission of hepatitis could have been developed before
20 1980." Heat treated, HIV-safe factor concentrates were not introduced by any Defendant until
21 1983, and were not universally in use until 1985.

22 50. In addition to heat treatment, solvent detergent treatment was available to
23 Defendants by the late 1970's as a simple and effective method of eliminating viruses in their
24 factor concentrate products. Solvent detergent effectively kills viruses such as HIV and HCV by
25 destroying the viruses' lipid envelope. It is simpler than heat treatment, and unlike heat treatment
26 does not interfere with the Factor VIII and IX proteins needed for blood clotting.

27 51. Solvent detergents were well-known, commercially available products as
28 of the 1970's, and studies in which solvent detergent treatment was used to disrupt viruses were

1 published in the 1970's in peer-reviewed journals. In 1980, Dr. Edward Shanbrom, a former
2 BAXTER scientist, received a patent for a solvent detergent treatment process for viral
3 inactivation of factor concentrate. Dr. Shanbrom describes the implementation of this process as
4 "as easy as washing your hands."

5 52. After receiving the patent, Dr. Shanbrom approached all four Defendants
6 about implementing the solvent detergent method, but all four Defendants wrongfully refused to
7 implement the method. With the exception of Defendant ARMOUR, Defendants refused to even
8 commit any resources to investigate the method. However, in June, 1985, the New York Blood
9 Center ("NYBC") obtained a license from the FDA to implement the process for Factor VIII. The
10 NYBC obtained a license to use the process in 1987. By 1987, all Defendants except ARMOUR
11 were using the process to virally inactivate their Factor VIII blood products.

12 53. Although heat treatment was effective in destroying the HIV virus, it was
13 ineffective in destroying HCV and HBV. A recent CDC study reported that "84% of previously
14 untreated patients infused with dry-heated Factor VIII products developed non-A, non-B hepatitis
15 ... several case reports of probable transmission of HBV and HCV through vapor heat-treated and
16 pasteurized products later appeared." (Risk Factor for Infection with HBV and HCV in a Large
17 Cohort of Hemophiliac Males: Soucie, Richardson, Evatt et al; Transfusion, 2001; 41:338-343)

18 54. The same CDC study reported that "solvent detergent treatment of blood
19 components found to be more effective against enveloped viruses than heat treatment ... No cases
20 of HBV, HCV, or HIV transmission through solvent detergent virus inactivated products have
21 been found in prospective studies of previously untreated patients..."

22 55. The study further reported "in our data, the first dramatic decline in HCV
23 prevalence appears in the 1987 birth cohort. The drop in HCV transmission correlates with the
24 licensing of solvent detergent treatment of factor IX products in 1987. In addition, this cohort
25 would have been the first to benefit from the screening of blood donors using the surrogate
26 markers ALT (begun in late 1986) and anti-HBc (begun in 1987), testing that was associated with
27 a markedly decreased risk of HCV infection from blood transfusions."

28 56. The study states further that "the residual transmissions after 1987 possibly

1 represent the use of product already manufactured or product manufactured during the interval
2 required to implement the new technology. The 18-month shelf life of factor concentrates placed
3 those hemophiliacs born as late as 1989 at risk of infection.” The study goes on to recommend
4 testing for all hemophiliacs who received infusions of the defendant’s blood products prior to
5 1992.

6 57. The failure of Defendants to implement solvent detergent viral inactivation
7 techniques in a timely manner, to warn of the risk that heat treated Factor VIII and IX blood
8 products could transmit HBV and HCV, and to recall heat treated products that posed this risk
9 caused the needless infection of thousands of hemophiliacs with HCV and HBV after 1984. Even
10 after Defendants knew or should have known that the solvent detergent process effectively
11 destroyed HCV and HBV, as well as HIV, they continued to sell heat treated Factor VIII and IX,
12 and refused to recall these dangerous products from the market.

13 **F. Defendants Continued to Ship Non-Heat Treated Factor Concentrate**
14 **Products Abroad Even After They Stopped Selling Non-Heat Treated**
Product in the United States

15 58. Between 1983 and 1985, Defendants stopped selling non-heat treated
16 factor concentrate in the United States and introduced a vastly safer heat-treated version.
17 However, one or more Defendants continued to ship their remaining stocks of non-heat treated
18 product abroad after ceasing sales of such product in the United States, despite knowledge that
19 the non-heat treated product was contaminated with HIV and/or HCV.

20 59. According to a New York Times article entitled “2 Paths of Bayer Drug in
21 1980’s: Riskier Type Went Overseas,” published on May 22, 2003, CUTTER, BAYER’s
22 predecessor, sold millions of dollars of non-heat treated factor concentrate in Asia and Latin
23 America for over a year after introducing its heat-treated product in the United States in February,
24 1984. According to the article, CUTTER records show that the company sought to maintain its
25 profit margin on “several large fixed-price contracts” in Latin America and Asia, and avoid being
26 stuck with old, unmarketable stock, by continuing to sell its cheaper-to produce non-heat treated
27 factor concentrate. Minutes from a CUTTER meeting in November, 1984 stated that “there is
28 excess nonheated inventory,” and that the company planned to “review international markets

1 again to determine if more of this product can be sold.” The company pursued this strategy even
2 though, according to the Times article, CUTTER’s manager for plasma procurement had
3 acknowledged in a letter in January, 1983 that “There is strong evidence to suggest that AIDS is
4 passed on to other people through ... plasma products,” and despite its knowledge that the CDC
5 had reported in October, 1984 that 74 percent of hemophiliacs who used unheated product were
6 HIV positive. The same CDC report indicated that a study done with CUTTER showed that heat
7 treatment rendered HIV “undetectable” in factor concentrate.

8 60. According to the Times article, in late 1984 CUTTER told a Hong Kong
9 distributor interested in its new heat-treated product to “use up stocks” of its old, non-heat treated
10 product first. CUTTER later assured the same distributor that the non-heat treated product posed
11 “no severe hazard.” In March 1985, a CUTTER report stated that “the Far East has ordered
12 400,000 units” and that “in Taiwan, Singapore, Malaysia, and Indonesia, doctors are primarily
13 dispensing nonheated Cutter” factor concentrate. CUTTER did not apply for a license to sell its
14 new heat-treated product in Taiwan until July 1985, over a year after it began selling the new
15 product in the United States. According to the Times article, over 100 hemophiliacs in Hong
16 Kong and Taiwan alone were infected with HIV by non-heat treated CUTTER product sold after
17 February, 1984.

18 61. The March, 1985 CUTTER report additionally states that “Argentina has
19 been sold 300,000 units,” according to the Times article. A total of 100,000 vials, or \$4 million
20 dollars worth, of non-heated CUTTER concentrate was shipped abroad after the company began
21 selling its heat-treated product in the United States.

22 62. CUTTER’s wrongful conduct in continuing to ship non-heat treated factor
23 concentrate abroad after ceasing sales of such product in the United States is typical of all
24 Defendants’ wrongful conduct worldwide. The Times article reports that upon learning of this
25 conduct in May, 1985, the FDA requested a meeting with Defendants to order them to comply
26 with their voluntary agreement to withdraw non-heat treated product from the market. According
27 to the Times article, Dr. Harry M. Meyer, at that time the FDA’s regulator of blood products,
28 stated in later legal papers that “[i]t was unconscionable for them to ship that material overseas.”

1 **G. Defendants Fraudulently Misrepresented the Safety of Factor VIII and IX**
2 **and Concealed the Dangers of the Products**

3 63. Defendants engaged in a pattern and practice of fraudulent concealment of
4 their dangerous practices, fraudulent misrepresentations of the extent of their efforts to assure
5 safety, and fraudulent misrepresentations that understated the risk of AIDS and Hepatitis C, in
6 order to maintain profits from both factor concentrates and HBIG. A summary of Defendants'
7 fraudulent misrepresentations and concealment is set forth below.

8 64. On July 27, 1982, a meeting of the Public Health Service was held as the
9 result of the CDC's report of three hemophiliacs who contracted AIDS. The responsible heads of
10 ARMOUR, ALPHA, CUTTER and BAXTER were in attendance, along with officials from the
11 National Hemophilia Foundation, CDC and FDA. Three of the four Defendants were aware that
12 they had used cryoprecipitate containing plasma from known, targeted homosexuals in the
13 manufacture of Factor VIII and IX blood products. These products had a shelf life of two and
14 three years, respectively, and were either in production or already on the shelves in pharmacies
15 waiting to be infused by hemophiliacs who purchased them. The Defendants involved, CUTTER,
16 BAXTER and ALPHA, failed to disclose these facts at the meeting where CDC officials Dr. Don
17 Francis and Dr. Jeff Koplin were present, despite knowledge that the CDC's primary concern at
18 that meeting was the infection of Factor VIII and IX by the transmitter of AIDS, which was
19 already well-known to be epidemic in the targeted homosexual population. (CUTTER
20 memorandum dated August 3, 1982)

21 65. In or about December, 1982, Rodell, the responsible head for BAXTER,
22 entered into an agreement with officials of the FDA to the effect that BAXTER would no longer
23 use prison plasma in the production of factor concentrates. In fact, BAXTER, unbeknownst to
24 the FDA, continued to use prison plasma in factor concentrate production through October 1983.
25 (BAXTER memorandum dated October 20, 1983.)

26 66. On January 5, 1983, an AIDS meeting was held at Children's Orthopedic
27 Hospital in Los Angeles, California, the largest hemophilia treatment center in the United States.
28 Representatives of all four Defendants were present at the meeting with treaters and patients. The

1 purpose of the meeting was to have Defendants' representatives answer patients' questions about
2 AIDS transmission through factor concentrates. A patient asked representatives from CUTTER,
3 ALPHA, ARMOUR and BAXTER the following question: "Is the plasma from homosexuals,
4 prisoners, Haitians or other high risk persons being used in the manufacture of concentrates?" No
5 Defendants admitted targeting or using plasma from homosexuals, prisoners or inner city IV drug
6 abusers. Dr. Goodman from BAXTER answered regarding BAXTER'S use of known
7 homosexuals as follows: "We are changing the nature of questions to homosexuals to the best of
8 our ability." CUTTER'S responsible head, Stephen Ojala, an ALPHA representative, and
9 ARMOUR'S Karl Hansen made no response to the question. This partial and misleading
10 response amounted to concealment of the true risk created by the use of known homosexuals, IV
11 drug abusers and prisoners in the manufacture of factor concentrates.

12 67. At the January 5, 1983 meeting, and in the presence of the patients, one of
13 the treating physicians, Dr. Kasper, asked CUTTER'S Stephen Ojala: "These [plasma] centers
14 seem to be in rundown centers of town. Is there a move to move them to rural towns?" Ojala
15 answered: "Many of the centers are in smaller communities and in towns such as Ypsilanti,
16 Seattle, Clayton, NC, and San Diego. We do not have centers in L.A. or San Francisco." This
17 answer was misleading because Ojala failed to state that CUTTER'S largest and first plasma
18 center was located at Arizona State Penitentiary. CUTTER also had a center at the Las Vegas
19 Prison. Ojala and CUTTER were well aware of the CDC's and FDA's concern over use of prison
20 plasma, due to homosexual practices and drug abuse in the prison donor population. Many of
21 CUTTER'S centers were in inner city areas frequented by IV drug abusers, such as downtown
22 Oakland, California. CUTTER had also used plasma from centers which targeted known
23 homosexuals. In August 1982, CUTTER quarantined plasma from the Valley Medical Center, a
24 center which targeted known homosexuals, because a donor was hospitalized with full blown
25 AIDS. The plasma was intended for Factor IX and HBIG production, but was not used because it
26 had thawed on the way to the processing plant. Upon receiving a report of this incident from
27 CUTTER, the FDA indicated a recall might have been necessary if the plasma had been
28 incorporated into factor concentrate final product. Ojala omitted any mention of these facts and

1 circumstances in his response to Dr. Kasper regarding the location of their plasma centers.
2 (CUTTER memorandum dated January 5, 1983.)

3 68. On January 14, 1983, Dr. Michael Rodell and the other responsible heads
4 from the four Defendants attended a meeting of the National Hemophilia Foundation ("NHF").
5 The purpose of the meeting was to have Defendants explain to the NHF what steps they were
6 prepared to take to safeguard the plasma supply from potential AIDS transmitters. Defendants
7 were very concerned that the NHF would insist on a recommendation that HBc testing be
8 implemented, consistent with the CDC recommendation 10 days earlier. BAXTER, under
9 Rodell's supervision, had already conducted a survey of several of their donor centers to
10 determine how many donors they would lose if the test were implemented. BAXTER had
11 decided that up to 16% of their donors would not pass the test. Further, BAXTER'S high titered
12 immunoglobulin donors would be eliminated. In order to defer an NHF recommendation that
13 HBc testing be used, Rodell told NHF officials that surrogate testing was in the "R and D," or
14 "Research and Development," stage currently. Rodell concealed the fact that the CDC had
15 strongly recommended use of the HBc Antibody test as a screening device for donors at high risk
16 for AIDS transmission. The HBc Antibody test was not in the "R and D" stage, and was suitable
17 for use as a screening device for high risk AIDS and Hepatitis C donors. In fact, the HBc test had
18 been approved in 1979 by the FDA as a diagnostic test to be used to ascertain a history of
19 previous hepatitis B infection, and as a screening device for blood and plasma donors. The test
20 had the capability of identifying all donors with a history of viral hepatitis. Donors with a
21 hepatitis history were specifically prohibited pursuant to the federal regulations (21 C.F.R.
22 § 640.63). Rodell acknowledged that implementation of the HBc test would eliminate high
23 titered immunoglobulin donors, but failed to disclose that opposition to use of the test was based
24 on economic rather than safety concerns.

25 69. At the January 14, 1983 meeting, ALPHA, CUTTER and BAXTER
26 concealed their advertising in publications distributed among urban homosexuals, for the specific
27 purpose of attracting them to plasma centers which supplied high titered plasma to the
28 Defendants. CUTTER and ALPHA concealed their extensive use of prison plasma, and

1 BAXTER discussed plans to phase out prison plasma during the coming year. However, none of
2 the Defendants revealed their "gentlemen's agreement" with the FDA to discontinue use of these
3 plasma sources immediately. (CUTTER Memorandum dated January 17, 1983.)

4 70. In response to the growing concern by hemophiliacs regarding reports in
5 the lay press of AIDS transmission through blood products, CUTTER issued a press release dated
6 January 28, 1983. The press release stated, "Cutter has intensively involved its people and
7 resources to contribute to a resolution of this segment of the AIDS problem." This statement was
8 false because CUTTER was, or had been, actively engaged in using the plasma of prisoners,
9 known homosexuals and inner city IV drug abusers in the manufacture of factor concentrates.
10 CUTTER had refused to comply with the CDC's recommendation to immediately implement the
11 HBc test to screen out these high risk donors, and was engaged in a conspiracy with the other
12 Defendants to conceal use of these donors in factor concentrates that were currently on the
13 market. CUTTER had formed an alliance with the other three Defendants to avoid timely
14 warnings, effective donor screening, and immediate recalls of high risk blood products. (ALPHA
15 Memorandum dated January 20, 1983.)

16 71. CUTTER published and distributed a magazine called ECHO, which was
17 intended for patients, treaters and pharmacies. The May 1983 issue of ECHO Magazine was
18 entitled, "Special AIDS Issue." In the introductory statement by CUTTER Medical Director
19 Dr. George Akin, the following representation appeared: "We at Cutter want you to know that
20 your welfare is our prime concern. We are doing everything possible to help researchers
21 diagnose the syndrome as well as implement precautionary measures designed to minimize the
22 risk for the person with hemophilia." This statement was false because:

23 a. CUTTER had engaged in concerted actions with the other three
24 companies to avoid recalls, timely warnings, appropriate HBc testing and screening of donors,
25 and the flow of accurate information through the NHF. They were engaged in aggressive
26 overpromotion of Factor VIII calculated to understate the risk of AIDS and Hepatitis C in order to
27 increase sales, which had dropped due to information reported in the lay press regarding the risks
28 of AIDS transmission. CUTTER, through its responsible head, Steven Ojala, was in the process

1 of organizing a coordinated legal defense plan to defend claims from AIDS victims they
2 anticipated as the result of their sales increases in 1983-84. In a January 1983 memorandum,
3 CUTTER discussed its plan to "refute links to AIDS."

4 b. CUTTER had failed to conduct any independent investigation into
5 any hemophiliac AIDS patient. CUTTER had been told by two of the foremost authorities in the
6 field, Dr. Lou Aledort and Dr. Peter Levine, that AIDS may be caused in hemophiliacs by foreign
7 proteins and alloantigens as well as unidentified viruses in the product, rendering continued use of
8 the products extremely dangerous. The product had been previously associated with chronic
9 active hepatitis, splenomegaly, lymphadenopathy, severe thrombocytopenia, T-cell abnormalities,
10 and high levels of circulating immune complexes. Older hemophiliacs were at increased risk for
11 full blown AIDS. These facts indicated that the more product infused, the higher the risk of
12 contracting AIDS.

13 c. Dr. Bruce Evatt of the CDC had informed CUTTER on March 15,
14 1983 that based upon the observed T-cell abnormalities in hemophiliacs, he expected one half of
15 them to develop full blown AIDS. The four fractionator Defendants were engaged in meetings
16 with the FDA with a common goal of averting a complete recall, the only responsible option
17 available to them.

18 d. CUTTER's Dr. Akin did not reveal that CUTTER was using or had
19 used a substantial amount of prison plasma, plasma from known homosexuals with a history of
20 Hepatitis B, and inner city dwellers with a high risk for intravenous drug abuse. These practices
21 exponentially increased the risk of AIDS and Hepatitis C, in direct contradiction to CUTTER's
22 misrepresentation that it was doing everything possible to minimize the risk.

23 72. In the May 1983 issue of ECHO, CUTTER published an article entitled
24 "AIDS, the Unfolding Story," in which the following statement appeared: "In addition, NHF is
25 working collaboratively with the CDC on a nationwide epidemiologic survey of all hemophilia
26 treatment centers and affiliates, and has obtained special federal funding for AIDS research for
27 the CDC plus increased funding for NIH." This statement was misleading because it did not
28 reveal the fact that the epidemiologic survey by the CDC and the NHF demonstrated that heavy

1 users of Factor VIII were displaying severe immune abnormalities and T-Cell imbalances, while
2 cryoprecipitate users were not displaying these abnormalities. The article does not disclose that
3 the CDC considered these hemophiliacs to be at increased risk for AIDS because of the immune
4 abnormalities reported in the survey by December, 1982. The statement was also misleading
5 because the NHF was presented as an independent authority, when the NHF was essentially a
6 channel for industry views. In fact, a 1993 report by the U.S. NIH Institute of Medicine
7 concluded that the NHF had serious "conflicts of interest" precluding objective analysis because
8 of its "interdependence" with the Defendants.

9 73. In the May 1983 ECHO article, CUTTER also understated the risk of
10 AIDS by presenting the view of Dr. Louis Aledort, Medical Co-Director of the NHF, and
11 hemophilia treater from New York's Mount Sinai Hospital. Dr. Aledort stated in the article, "Put
12 AIDS Disease in Perspective," as follows: "AIDS should not be viewed as a "panic signal" or a
13 reason to change a hemophilia patient's therapy." CUTTER chose to print this statement in
14 enlarged text. The statement was false and misleading because many physicians had in fact
15 already changed their patient's therapy based on scientific evidence of AIDS being cause by
16 Factor VIII and IX. There was substantial evidence to justify a change in therapy and a complete
17 recall of unscreened Factor VIII by May 1983.

18 74. Dr. Aledort's article in the ECHO of May 1983 went on to state: "There is
19 no evidence to support that AIDS is transmitted in either cryoprecipitate or concentrate, although
20 it is possible." This statement was directly contrary to the evidence which led the Public Health
21 Service ("PHS") to conclude, following the January 4, 1983 CDC meeting, that donors at risk for
22 AIDS transmission should be screened to eliminate them from the blood supply. The statement
23 also ignores the March 24, 1983 PHS recommendations regarding mandatory screening
24 guidelines for blood and plasma donors to reduce the risk of AIDS transmission, because of the
25 evidence supporting transmission of AIDS in factor concentrate. It is also contrary to
26 Dr. Aledort's repeated assertions, in sworn testimony at trials and in depositions, that it was his
27 expert opinion that AIDS was transmitted through factor concentrates by repeated exposure to
28 foreign proteins and alloantigens in intermediate purity factor concentrates until 1984, when the

1 AIDS virus was isolated and identified. (ECHO Magazine, May, 1983 "Special AIDS Edition")

2 75. CUTTER conducted an AIDS Forum in the Summer of 1983 at the World
3 Hemophilia Federation Meeting in Stockholm, Sweden. CUTTER invited several hemophilia
4 treatment experts to participate in the forum. CUTTER later published the statements made by
5 some of the experts in a publication entitled "Cutter Forum: AIDS and Hemophilia Treatment."
6 In the publication the following statements were selected by CUTTER for attribution to the
7 experts: "The physician who wants to test a patient for AIDS runs the risk of putting the patient
8 into a state of terror." "Many at the conference warned colleagues to avoid fueling patients' fears
9 by giving them inconclusive data." "The major concern I have is that physicians or others who
10 deliver healthcare will magnify the panic by telling patients they have 'pre AIDS' or AIDS, based
11 on the methodology we have used for the last four or five years in defining T-Cell populations."
12 Another M.D. added, "With the anxiety our fellow physicians are causing patients, we're going to
13 see more fear of AIDS than actual cases of AIDS." The statements attributed to these "experts"
14 are misleading. In fact there was no medical or scientific support for any of the anonymous
15 conclusions stated by the "M.D.'s" in the article. By the summer of 1983, T-cell testing was
16 sufficiently reliable to form the basis of numerous reliable studies and conclusions about AIDS in
17 hemophiliacs and other risk groups. There was no scientific methodology to support the
18 statement that the fear of AIDS would outnumber actual AIDS cases. Instead, CUTTER'S
19 motive was to understate the risk and increase sales, while continuing to conceal the use of high
20 risk plasma to manufacture Factor VIII and IX.

21 76. The CUTTER 1983 "Forum" article also attributed the following statement
22 to an "expert" treater: "A physician who has dealt with AIDS directly also doubted the validity of
23 T-Cell tests." This statement was false because by the summer of 1983, T-cell abnormalities over
24 time were a clear risk factor for AIDS. The article also stated, "Another M.D. added, 'I have to
25 sit down individually with all the patients and discuss the AIDS problem with them. But I stress
26 that I am not very concerned because the majority of our hemophiliacs are not affected by it.'"
27 This statement was very misleading because the growing epidemiological evidence regarding
28 AIDS in hemophiliacs clearly supported a substantial risk due to their extensive use of factor

1 concentrates, and Defendants knew of CDC projections that half of all hemophiliacs would
2 develop AIDS.

3 77. The CUTTER 1983 "Forum" article went on to state: "One researcher put
4 the situation into perspective this way: 'The very essence of our treatment programs could
5 potentially be threatened by the fear of a disease that has not even killed ten hemophiliac people
6 since 1982... I had eight patients die of trauma and cerebral hemorrhage last year, and I didn't
7 have any die of AIDS. I think we have to remember that our patients are getting hit on the head
8 or mugged, that they're falling down stairs, they're bleeding to death, and that those problems are
9 much more immediate than anything having to do with AIDS.' This statement was misleading
10 because in the summer of 1983, CUTTER conducted an analysis which acknowledged the risk of
11 2,000 to 5,000 hemophiliac deaths in the United States due to AIDS transmission through factor
12 concentrates.

13 78. The above statement is also misleading in that it perpetuated the false
14 dichotomy between the benefits of factor concentrate therapy and the risk of AIDS. In fact, the
15 benefits of such therapy could and should have been provided with little or no AIDS risk by
16 avoiding use of high risk homosexual and IV drug user donors, treating plasma to kill viruses, and
17 implementing the HBc test. This statement was also contrary to the medical, scientific and
18 epidemiological evidence in existence at the time of the conference seminar on July 1, 1983. The
19 risk of contracting AIDS was already close to one in 100 for severe type A hemophiliacs. If T-
20 cell abnormalities were taken into consideration, the risk was close to one out of two for heavy
21 users of the product. As noted previously, the CDC had predicted several months before the
22 CUTTER Forum was published that 50% of hemophiliacs would suffer from full blown AIDS.
23 (CUTTER document entitled "Cutter Forum, AIDS and Hemophilia Treatment" around July 1,
24 1983)

25 79. In late October 1983, CUTTER was notified that a donor had died of AIDS
26 in Austin, Texas. The donor died within 30 days of his last donation. Because the donor's
27 plasma had been used in numerous lots of Factor VIII and IX over the previous two years, a recall
28 of those lots was ordered by CUTTER. On November 1, 1983, CUTTER issued a press release

1 regarding the recall. The press release stated, "No adverse reactions involving these lots have
2 been reported." This statement is misleading because it was virtually impossible for CUTTER to
3 know whether or not any adverse reactions had been experienced or reported to physicians by
4 patients who infused lots which contained plasma from the AIDS donor. The withdrawal
5 pertained to several lots and involved the pooling of the AIDS donor's plasma in thousands of
6 doses of factor concentrate. In fact, abnormal T-cell ratios had undoubtedly been reported in
7 some hemophiliacs who infused lots containing the AIDS donor's plasma, along with
8 lymphadenopathy and numerous other side effects associated with a pre-AIDS condition.

9 80. CUTTER further stated in the November 1, 1983, press release, "Although
10 medical authorities consider the possibility of AIDS being transmitted through these products
11 exceedingly remote, CUTTER is taking the action on its own initiative as a precautionary
12 measure." This statement is false because public health authorities from the CDC had advised
13 CUTTER on March 15, 1983 that they expected one-half of the hemophilia patients who had
14 infused these products to develop full blown AIDS. CUTTER had been repeatedly advised by
15 public health officials that the AIDS observed in persons at risk for AIDS was only the "tip of the
16 iceberg." CUTTER had conducted its own in-house investigations entitled "AIDS scenarios" and
17 concluded that a possible outcome would be full blown AIDS in 5,000 hemophiliacs in the U.S.
18 There was a public health consensus that hemophiliacs were one of the high risk groups for
19 contracting AIDS because of their use of Factor VIII. CUTTER was within days of applying to
20 the FDA for a change to the labeling of Factor VIII that would include a stronger warning.
21 (CUTTER Press Release dated November 1, 1983)

22 81. ALPHA published and distributed a newsletter in the summer of 1983
23 entitled "Hemophilia." The newsletter contains the statement in an introduction by Thomas
24 Stagnaro, Marketing Head, that "[n]eedless to say, Alpha has stepped up efforts to protect
25 hemophilia patients, but new evidence suggests there is no proof that AIDS is necessarily
26 associated with blood or blood products." This statement was misleading because it was contrary
27 to existing and accumulating scientific evidence demonstrating the associated risk between use of
28 Factor VIII and AIDS. It was also contrary to the PHS guidelines and recommendations of

1 January 4 and March 24, 1983 mandating screening of high risk donors for AIDS.

2 82. The ALPHA 1983 newsletter also stated: "There is some question as to
3 whether use of cryoprecipitate would actually be safer in any case." This statement was contrary
4 to the consensus that cryoprecipitate was safer because it was made from voluntary donors in
5 groups of 8 to 10, while ALPHA's product was made using pools of plasma from high risk paid
6 donors, with 5,000 to 40,000 donations in each lot. Immune abnormalities had been associated
7 with use of factor concentrates but not cryoprecipitate. Thus, there was no credible evidence
8 upon which to question the fact that cryoprecipitate was safer than factor concentrates.
9 (Hemophilia Letter, dated Summer, 1983, Vol. 5, No. 1.)

10 83. ALPHA organized a seminar consisting of hemophilia treaters and
11 physicians from the CDC and NIH in connection with an American Blood Resources Association
12 ("ABRA") meeting held in Puerto Rico in March, 1983, called the "ABRA Plasma Form." All
13 Defendants were members of ABRA, and ABRA itself held meetings of Defendants for the
14 purpose of planning strategies to understate the AIDS risk. ALPHA published excerpts from the
15 1983 Forum which understated the risk of factor concentrate in comparison to other therapies,
16 such as the statement attributed to Dr. Lou Aledort of the NHF: "[M]ore recent, unpublished data
17 show that immune system abnormalities develop in hemophiliacs no matter what sort of treatment
18 they receive, concentrate or cryo, Factor VIII or IX, high doses or low, and whether they are
19 young or old, or whether their disease is mild, moderate or severe." Dr. Aledort also cautioned
20 that "measuring T-Cell changes is technically difficult, and that the methodology used in some
21 studies has been faulty." This statement was contrary to the medical and scientific evidence
22 existing at that time. Older, more severe hemophiliacs who had used more product were
23 demonstrating more severe immune abnormalities, as well as opportunistic infections. Factor
24 VIII users, who were exposed to greater quantities of concentrate, were more immune suppressed
25 than Factor IX users. Cryoprecipitate users had fewer immune abnormalities than concentrate
26 users.

27 84. The 1983 ALPHA/ABRA Forum includes the following statement,
28 attributed to Dr. Nemo: "It is not at all clear, Dr. Nemo said, that an infectious AIDS agent, if

1 one exists, can be spread by blood products. The link between AIDS and its possible
2 transmission by blood products is very tenuous indeed.” This statement was demonstrably false
3 by March, 1983, by which time the overwhelming scientific evidence supported the conclusion
4 that AIDS was transmitted by blood products such as factor concentrates. (Highlights from the
5 1983 ABRA Plasma Forum, A Professional Service of Alpha Therapeutic Corporation, March
6 1983.)

7 85. On or about December 15, 1983, Rodell, then the head of ARMOUR, told
8 members of the federal Blood Product Advisory Committee (BPAC) and FDA officials that the
9 Defendants wanted a three month deferral in implementation of any recommendations by the
10 BPAC or FDA that HBc testing be required for plasma donors. Rodell told the FDA that the
11 purpose of the deferral was to prepare a response to the proposed recommendation. In fact, all
12 Defendants had agreed to seek the three month hiatus as a “delaying tactic” against implementing
13 the test, and the request for a deferral was made in bad faith. (CUTTER memorandum dated
14 December 13, 1983.)

15 86. The September 1985 issue of ECHO magazine also contained a number of
16 false and misleading statements. In the magazine, CUTTER stated, “The ability to screen donors
17 was hampered by not knowing what caused the disease. However, as soon as it became known
18 that there was a possibility of transmitting AIDS through blood products, Cutter Laboratories
19 began to screen donors in an effort to exclude any who were in the high risk groups.” This
20 statement was misleading because there was no need to determine what actually caused Factor
21 VIII to transmit AIDS in order for CUTTER to screen out donors who were at high risk for AIDS
22 transmission. It was strongly suggested by the CDC on July 27, 1982, that AIDS had a viral
23 etiology similar to Hepatitis B because of the risk groups involved. These risk groups comprised
24 a substantial portion of CUTTER’s plasma donor sources. CUTTER took no meaningful action
25 to screen out donors at the highest risk for AIDS and Hepatitis C transmission at any time during
26 the epidemic. In fact, they continued to market products containing plasma from these groups
27 throughout 1982, 1983 and 1984 worldwide. Even more egregiously, CUTTER and other
28 Defendants continued to market high risk non-heat treated factor concentrate abroad after ceasing

1 sales of such product in the United States in favor of vastly safer heat treated product.

2 87. In the same issue of ECHO, Dr. Margaret Hilgartner, a hemophilia treater
3 from Cornell Medical Center presented by CUTTER, made the following statement understating
4 the risk of AIDS and exaggerating the need for factor concentrate products: "The current risk of
5 persons with hemophilia developing AIDS is directly related to their need for blood products to
6 stop bleeding. The risk is extremely low. Although most persons with hemophilia who have
7 been treated with concentrate and some who have been treated with cryoprecipitate have been
8 exposed to the virus in the past, less than .1 percent of the 20,000 persons with hemophilia in the
9 United States have developed AIDS." This statement was misleading for several reasons:

10 a. The risk was very close to 1% for severe type A hemophiliacs, who
11 were the heaviest users and most likely to be exposed to HIV in Factor VIII. The CDC had
12 reported 71 cases in such persons by September 1985. Since there were approximately 8,000
13 severe, Type A Hemophiliacs using the product regularly, the risk was close to one in 100. A 1 %
14 risk of contracting AIDS, a fatal disease, is not "low" as stated by Dr. Hilgartner. Dr. George
15 Akin, CUTTER's medical director, repeated this misrepresentation in his forward to the
16 Hilgartner article in the ECHO publication.

17 b. The article did not disclose the report made by Dr. Evatt of the
18 CDC to the company at a March 1983 ABRA meeting, in which he projected that one half of all
19 hemophiliacs would get full blown AIDS based upon their known T-Cell abnormalities tied to
20 exposure to Factor VIII. (CUTTER memorandum dated March 14, 1983.)

21 c. As they had done throughout, Defendants misleadingly represented
22 that the benefits of Factor VIII outweighed the risks of AIDS and Hepatitis C, when in fact the
23 benefits could and should have been provided with minimal risk through proper safety measures
24 and avoiding high risk donors.

25 88. In the same issue of ECHO, Dr. Hilgartner further stated, "[A] positive test
26 result does not mean that the person will actually get AIDS." This statement was misleading
27 because there was no scientific basis for concluding in September 1985 that a positive ELISA
28 test, the then-existing test for the presence of HIV antibodies, did not mean eventual full blown

1 AIDS in the patient. In fact, severe T-Cell abnormalities and a positive ELISA test were reliable
2 predictors of full blown, and eventually fatal, AIDS.

3 89. Dr. Hilgartner's article states, "There is no evidence to warrant changing
4 the current use of Factor VIII or Factor IX." This statement was also false. In fact, the evidence
5 was just the opposite. Non-heat treated, intermediate purity products were known by September
6 1985 to be contaminated with HIV by virtue of testing done at the CDC in the summer of 1984.
7 These tests demonstrated that 70% of type A severe and 40% of type B hemophiliacs were HIV
8 positive. In addition, Dr. Hilgartner had reported to the New York Academy of Sciences in 1983
9 that Factor VIII was associated with extremely serious side effects, including loss of
10 lymphocytes, thrombocytopenia, liver damage, renal failure, splenomegaly and abnormally high
11 levels of circulating immune complexes. Many of these same diseases were reported in
12 hemophiliac AIDS victims. Thus, there was strong medical and scientific evidence that continued
13 use of non-heat treated, intermediate purity factor concentrates should be avoided. (ECHO
14 magazine Vol. 6, No. 3, dated September 1985.)

15 90. These facts demonstrate that Defendants, jointly and individually,
16 fraudulently misrepresented the risk of AIDS and Hepatitis C due to factor concentrates, failed to
17 disclose accurate warnings of the risk to Decedent or his physicians, and fraudulently purported to
18 be doing "everything possible" to improve safety, when in fact Defendants maximized the risk by
19 recruiting high risk donors and by resisting and obstructing HBc testing, heat treatment, and other
20 measures that would truly have reduced the risk.

21 **H. Defendants' Activities Were Subject to Applicable Federal Regulations,**
22 **Which Evidences the Standard of Care With Which Defendants Should Have**
23 **Complied**

24 91. Blood derivatives such as Factor VIII and IX are prescription biologicals
25 subject to federal regulation as both "biological products" and "drugs." Public Health Service
26 Act, "Regulation of Biological Products," 42 U.S.C. § 262; Food, Drug & Cosmetic Act
27 ("FDCA"), 21 U.S.C. § 301, et seq.

28 a. 21 U.S.C. § 331(b) prohibited [should these be present tense
instead?] "adulteration or misbranding of any . . . drug, . . ."

b. 21 U.S.C. § 51(a)(2)(B) provided that “[a] drug . . . shall be deemed to be adulterated . . . if . . . the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this chapter as to safety”

c. 21 U.S.C. § 352 provided that “[a] drug . . . shall be deemed to be misbranded . . . if its labeling is false or misleading in any particular.”

d. 21 U.S.C. § 352(0)(2) provided that a drug shall be deemed to be “misbranded” unless its labeling bears “adequate warnings against use . . . where its use may be dangerous to health.”

e. 21 U.S.C. § 352(n) provided that a drug shall be deemed to be “misbranded” unless the labeling included information concerning side effects and contraindications as required in federal regulations.

f. 21 U.S.C. § 321(n) provided that if an article is alleged to be misbranded because the labeling or advertising is misleading, then the determination of whether the labeling or advertising is misleading shall take into account “not only representations made or suggested” by affirmative statements, “but also the extent to which the labeling or advertising fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use” of the drug.

92. At all times material to this Complaint, 21 C.F.R. § 201.57(e) provided as follows, with respect to information to be provided with the sale of Defendants’ products:

Warnings: Under this section heading, the labeling shall describe serious adverse reactions and potential safety hazards, limitations in use imposed by them, and steps that should be taken if they occur.

The labeling shall be revised to include a warning as soon as there is reasonable evidence of an association with a drug; a causal relationship need not have been proved.

93. At all times material to this Complaint, 21 C.F.R. § 200.5 provided as

1 follows:

2 Manufacturers and distributors of drugs and the Food and Drug
3 Administration occasionally are required to mail important
4 information about drugs to physicians and others responsible for
5 patient care. In the public interest, such mail shall be distinctive in
6 appearance so that it will be promptly recognized and read.

7 94. At all times material to this Complaint, Part 606 of 21 C.F.R. set forth
8 "Current Good Manufacturing Practices" for biological products generally, and 21 C.F.R. § 640,
9 et seq., set forth additional good manufacturing practices for blood and plasma biologicals.

10 95. At all times material to this Complaint, 21 C.F.R. § 606.140(a) provided:
11 Laboratory control procedures shall include: The establishment of
12 scientifically sound and appropriate specifications, standards and
13 test procedures to assure that blood and blood components are safe,
14 pure, potent and effective.

15 96. At all times material to this Complaint, 21 C.F.R. § 640.60 defined "Source
16 Plasma (human)" as:

17 The fluid portion of human blood which has been stabilized against
18 clotting, collected by plasmapheresis, and is intended as source
19 material for further manufacture into blood derivatives (a portion of
20 pooled plasma separable by chemical means) intended for injection.

21 97. At all times material to this Complaint, 21 C.F.R. § 640.63(c), entitled
22 "Qualification of Donor," provided as follows with respect to donors of source plasma:

23 Donors shall be in good health on the day of donation, as indicated
24 in part by: . . . (9) freedom from any disease, other than malaria,
25 transmissible by blood transfusion, in so far as can be determined
26 by history and examination indicated in this section; (10) freedom
27 of the arms and forearms from skin punctures or scars indicative of
28 addiction to self- injected narcotics; (11) freedom from a history of

1 viral hepatitis; (12) freedom from a history of close contact within
2 six months of donation with an individual having viral
3 hepatitis;

4 Further, 21 C.F.R. § 640.63(a) provided that the method of determining "suitability of a donor"
5 included "tests" as well as the taking of a history and physical examination.

6 98. At all times material to this Complaint, 21 C.F.R. § 606.140 provided as
7 follows:

8 Laboratory control procedures shall include: (a) The establishment
9 of scientifically sound and appropriate specifications, standards and
10 test procedures to ensure that blood and blood components are safe,
11 pure, potent and effective.

12 99. The foregoing statutes and regulations are evidence of the standard of care
13 Defendants should have employed in the manufacture and sale of Factor VIII and Factor IX.
14 Defendants violated the foregoing regulations and/or failed to comply with applicable standards
15 of care by: (a) marketing "adulterated" products that were unsafe as a result of failure to comply
16 with "Current Good Manufacturing Practice"; (b) marketing "misbranded" products that were
17 misleading and failed to disclose or warn of health dangers; (c) failing to warn of serious adverse
18 reactions and potential safety hazards as soon as there was reasonable evidence of an association
19 with the product; (d) failing to exclude intravenous drug users who were unsuitable donors;
20 (e) failing to exclude donors with a history of viral Hepatitis who were unsuitable donors;
21 (f) affirmatively seeking out unsuitable donors known to have viral Hepatitis antibodies, as well
22 as prison populations known to include substantial numbers of intravenous drug users, for
23 inclusion of their plasma in the pools used to make Factor VIII and Factor IX; (g) failing to
24 disclose their use of dangerous donors; and (h) failing to use appropriate tests and/or procedures
25 to assure the products were safe.

26 **V. CONSPIRACY, CONCERT OF ACTION AND GROUP LIABILITY**

27 100. Defendants, and each of them, acted in concert and participated in a
28 conscious and deliberate conspiracy to act negligently, fraudulently and with willful and wanton

1 disregard for the rights and safety of blood product users, in connection with the manufacture of
2 Factor VIII and IX blood products and the collection of constituent plasma.

3 101. After 1978, there were only four corporations in the United States engaged
4 in the production of Factor VIII and IX. These four companies, Defendants herein, tacitly and
5 explicitly agreed to avoid upgrading industry standards. For example, the technology to virally
6 inactivate factor concentrates existed in the early 1970s, but was not seriously investigated by any
7 of the Defendants until the early 1980s, despite its effective use in Europe. Use of the HBc
8 antibody test to eliminate Hepatitis B carrier donors, and to identify donors with a history of viral
9 Hepatitis, was known science by 1978. The HBc test was reported to be an effective surrogate
10 test for both AIDS transmission and NANB Hepatitis carriers by 1982, yet no Defendant
11 implemented this test until April 1984.

12 102. Three of the Defendants, ALPHA, BAXTER and CUTTER, used donors
13 from predominantly homosexual donor centers, prisons, and inner city areas where the risk of IV
14 drug abuse was high. After July 1982, when the results of this conduct culminated in reports of
15 fatal immune suppression in three hemophiliacs who infused the product, this concert of action
16 took on a more overt, active form.

17 103. By December 1982, the FDA demanded that Defendants stop using
18 prisoners, donors from high risk areas for hepatitis and AIDS transmission, and known
19 homosexuals. Rather than use good faith efforts to comply with the FDA requests, Defendants
20 collectively argued for a far less onerous and less effective donor screening program. They
21 jointly proposed a system comprised of educating the donor by posting a placard in the donor
22 center stating who the risk groups for AIDS transmission were, and advising the donor that he
23 would be deferred if he acknowledged he was a member of one of those groups. Later, he would
24 be required to fill out a questionnaire in private. If he checked the box indicating he was in a high
25 risk group, he would be permanently deferred.

26 104. At a January 6, 1983 meeting of Defendants' trade association, the
27 Biological Section of the Pharmaceutical Manufacturer's Association ("PMA"), Defendants
28 agreed not to implement highly effective HBc donor screening, instead selecting ineffective donor

1 questionnaires that did little to screen out donors at high risk for AIDS transmission. Defendants
2 further agreed to keep each other informed as to what the other was doing in order that a low
3 standard of care was maintained. HBc testing had been strongly suggested by the CDC at the
4 January 4, 1983 Public Health Service ("PHS") meeting. On January 14, 1983, Defendants acted
5 jointly to persuade the National Hemophilia Foundation ("NHF") not to advocate surrogate
6 testing for AIDS and Hepatitis C through implementation of the HBc test. Defendants persuaded
7 the NHF that use of the HBc test was in the "R and D" stage and not practical to implement at
8 that time.

9 105. Defendants jointly agreed to oppose recall of the products beginning at the
10 January 6, 1983 meeting at the Pharmaceutical Manufacturers' Association ("PMA"). Beginning
11 with this meeting and continuing through at least July 19, 1983, Defendants met at various times
12 to prepare a strategy to prevent the FDA from advocating a far-reaching recall of factor
13 concentrate products. Defendants knew that due to their high risk donor populations, and their
14 combining of these donors in pools of 5,000 to 40,000, that their products were contaminated
15 with the AIDS agent. Nevertheless, Defendants acted in concert to lobby the FDA, to get the
16 FDA to issue recommendations to limit recalls to circumstances in which an identified donor had
17 died of AIDS within a specified time after the pooling of that donor's plasma. Defendants were
18 well aware that plasma from contaminated asymptomatic donors were mixed in the plasma pools
19 and contaminated virtually all lots. Defendants were successful in deferring any FDA Blood
20 Products Advisory Committee ("BPAC") recommendation for a general recall of the product at
21 the July 19, 1983 BPAC meeting. This joint action allowed the defendants to avoid ever recalling
22 any product except when a donor died of AIDS.

23 106. Defendants conducted a meeting on or about January 6, 1983 at the PMA, a
24 major purpose of which was to decide on a unified strategy to deal with increasing knowledge of
25 risk of AIDS. At the meeting all four companies agreed to postpone submitting any request to the
26 FDA for permission to amend their warning labels or package inserts. They further agreed not to
27 apply to the FDA for warnings enhancements until the other three companies agreed to make
28 application for warning enhancements and to make the warnings similar in content. At the time

1 of the meeting, Defendants had been informed by various reliable health authorities, including the
2 PHS, that there was evidence of an association of risk between factor concentrate use and the
3 transmission of AIDS.

4 107. On December 13, 1983, Stephen Ojala, CUTTER's responsible head,
5 documented by written memorandum that Defendants met and jointly agreed to propose a "study"
6 of the HBc surrogate screening test, as a "delaying tactic" to avoid implementing the HBc test.

7 108. Thereafter, at various times throughout 1983-1985, Defendants attended
8 meetings or otherwise communicated to assure joint efforts to avoid recalling product; to avoid
9 warning patients of the true risk; to market product when sales dropped due to information in the
10 lay press related to AIDS transmission through factor concentrates; to avoid recall of non-heat-
11 treated product after heat-treated products were available; to avoid implementation of the HBc
12 test; and to coordinated a joint legal defense plan in anticipation of litigation from patients
13 afflicted by AIDS through use of the products. Defendants also operated through trade
14 organizations, such as ABRA and PMA, to issue public statements minimizing the risks of AIDS
15 and Hepatitis C and overpromoting the benefits of factor concentrate, to carry out the
16 abovementioned goals of all Defendants.

17 109. All of the Defendants likely to have caused the harm to Plaintiff and to
18 Decedent are parties to this lawsuit and properly before the court.

19 110. The conduct of each and all of the Defendants, with respect to their Factor
20 VIII and Factor IX products and related plasma collection methods, was tortious.

21 111. The harm which has been caused to the Plaintiff and Decedent resulted
22 from the conduct of one, or various combinations of the Defendants, and, through no fault of the
23 Plaintiff or Decedent, there may be uncertainty as to which one or combination of Defendants
24 caused the harm.

25 112. The burden of proof should be upon each Defendant to prove that the
26 Defendant has not caused the harms suffered by Plaintiff or Decedent.

27 113. AHF was manufactured using the same fractionation method by all
28 Defendants. As such, during the relevant years from 1975 until 1985, factor concentrates were a

1 fungible product, and physicians prescribed the products interchangeably without regards to
2 brand names of the drugs.

3 114. The factor concentrates manufactured by Defendants from 1975 until 1985
4 contained the same design flaws. They were all manufactured from paid donor plasma, which
5 was at highest risk for Hepatitis B, Hepatitis C, and HIV viral transmission. In addition, the
6 factor concentrate was made from large pools consisting of 5,000 to 40,000 paid donors, which
7 further magnified the risk of viral transmission.

8 115. None of the factor concentrate was virally inactivated during this time
9 period. Therefore, all of the AHF carried a significant risk of viral transmission. In addition, all
10 of Defendants' factor concentrate products were similarly misbranded. All of the products failed
11 to warn of the known risks enumerated in this complaint.

12 116. In large part because of the fungibility of Defendants' factor concentrate
13 products, many hemophiliacs infused products from two or more of the Defendants during the
14 time period when all of the Defendants' products were infectious for HCV and HIV. It therefore
15 may not be possible to determine which of the Defendants' products actually caused Decedent's
16 infection. By suing the named Defendants, Plaintiff has joined all those manufacturers who could
17 have caused the infection with HCV and HIV. Plaintiff alleges that Defendants have joint,
18 several, and alternative liability for Plaintiff's injuries.

19 117. Plaintiff in this case will make all reasonable efforts through discovery and
20 use of experts to make a good faith determination as to which of the Defendants' product(s)
21 caused the Decedent's HCV and/or HIV infections. However, if it is not possible to make such a
22 determination, Plaintiff respectfully requests that in the event that she prove that one or more
23 Defendants breached a duty to Plaintiff or Decedent that caused Decedent's infection with HIV
24 and/or HCV, but it cannot be proven which Defendants' product(s) caused this harm, the court
25 award damages consistent with each Defendant's market share at the relevant time.

26 **VI. TOLLING OF APPLICABLE STATUTES OF LIMITATION**

27 118. Any and all potentially applicable statutes of limitations have been tolled
28 by Defendants' affirmative and intentional acts of fraudulent conduct, concealment, and

1 misrepresentation, alleged above, which estop Defendants from asserting statutes of limitation.
2 Such acts include but are not limited to intentionally covering up and refusing to disclose use of
3 high risk plasma; sale of products abroad known to be contaminated; suppressing and subverting
4 medical and scientific research; and failing to disclose and suppressing information concerning
5 the risks of HIV and HCV transmission from Defendants' contaminated factor concentrate. For
6 example, while the spread of AIDS in homosexuals and IV drug users became known to the FDA
7 and the public, only Defendants knew that these very populations were the donors Defendants
8 were targeting to obtain plasma for their factor concentrate products.

9 119. Defendants are estopped from relying on any statutes of limitation because
10 of their fraudulent concealment and misrepresentation alleged above. Defendants were under a
11 duty to disclose the risks of HIV and HCV transmission from their contaminated factor
12 concentrate because this is nonpublic information over which they had exclusive control, because
13 Defendants knew this information was not readily available to Plaintiff or Decedent, and because
14 this information was relevant to Decedent in deciding whether to use Defendants' factor
15 concentrate.

16 120. Until very recently, Plaintiff had no knowledge that Defendants were
17 engaged in much of the wrongdoing alleged herein. Because of the fraudulent and active
18 concealment of the wrongdoing by Defendants, including but not limited to deliberate efforts-
19 which continue to this day-to give Plaintiff the materially false impression that Defendants
20 undertook all feasible safety precautions to reduce the risk of HIV and HCV transmission from
21 their contaminated factor concentrate, Plaintiff could not reasonably have discovered the
22 wrongdoing any time prior to this time, nor could Plaintiff have, as a practical matter, taken
23 legally effective action given the unavailability, until very recently, of internal memoranda and
24 other documents (as generally described herein) as evidence in support of Plaintiff's claims.
25 Defendants still refuse to admit and continue to conceal their wrongdoing, and therefore
26 Defendants' acts of fraudulent concealment and misrepresentation continue through the present
27 time.
28

VII. CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF

NEGLIGENCE (SURVIVAL ACTION)

121. Plaintiff incorporates by reference all previous paragraphs of this Complaint as if fully set forth here and further allege as follows:

122. Defendants marketed their Factor VIII and/or Factor IX blood products to and for the benefit of Plaintiff's Decedent, and knew or should have known that Plaintiff's Decedent would use their Factor VIII and/or Factor IX blood products.

123. Defendants owed Plaintiffs' Decedent duties to exercise reasonable or ordinary care under the circumstances in light of the generally recognized and prevailing best scientific knowledge.

124. Through the conduct described in the foregoing and subsequent paragraphs of this Complaint, the Defendants breached their duties to Plaintiff Decedent. The following sub-paragraphs summarize Defendants' breaches of duties to Plaintiff's Decedent and describe categories of acts or omissions constituting breaches of duty by Defendants; each and/or any of these acts or omissions establishes an independent basis for Defendants' liability in negligence:

a. Failure to exercise reasonable care in producing Factor VIII and Factor IX blood products that were free of viruses, including the HIV virus that causes AIDS and the HCV virus that causes Hepatitis C;

b. Failure to exercise reasonable care in assuring that only suitable plasma would be used in manufacturing Factor VIII and Factor IX blood products;

c. Failure to exercise reasonable care in testing plasma used in manufacturing Factor VIII and Factor IX blood products for virus contamination;

d. Failure to exercise reasonable care in recruiting and screening donors of plasma used in manufacturing Factor VIII and Factor IX blood products;

e. Failure to reasonably employ anti-viral techniques, including heat treating, in the manufacture of Factor VIII and Factor IX blood products;

f. Unreasonable overpromotion of Factor VIII and Factor IX blood

1 products;

2 g. Understating the relative value of hemophilia treatments that
3 constituted alternatives to Defendants' Factor VIII and Factor IX blood products;

4 h. Failure to warn physicians, Plaintiff, and the hemophiliac
5 community of the dangers associated with Factor VIII and Factor IX blood products and/or the
6 viruses and foreign bodies contained within the plasma used in manufacturing Factor VIII and
7 Factor IX blood products;

8 i. Failure to exercise reasonable care by complying with federal
9 regulations then applicable to plasma collection and the manufacture of Factor VIII and Factor IX
10 blood products.

11 j. Failure to exercise reasonable care in disseminating information
12 about Defendants' methods of manufacturing Factor VIII and Factor IX blood products and the
13 risks that were created by said methods; and

14 k. Failure to exercise reasonable care in recalling Factor VIII and
15 Factor IX blood products.

16 125. Defendants knew, or should have known, that, due to their failure to use
17 reasonable care, Plaintiff's Decedent and other people with hemophilia, would use and did use
18 Defendants' Factor VIII and/or Factor IX products to the detriment of their health, safety and
19 well-being.

20 126. As the direct, producing, proximate and legal cause and result of the
21 Defendants' negligence, Plaintiff's Decedent suffered death

22 127. Plaintiff is therefore entitled to damages in an amount to be proven at trial,
23 together with interest thereon and costs.

24 128. Defendants' conduct, as alleged above, was malicious, intentional and
25 outrageous and constituted willful and wanton disregard for the rights or safety of others. Such
26 conduct was directed specifically at Plaintiff's Decedent and was such as warrants an award of
27 punitive damages.

28 129. The aforesaid cause of action has survived to the Plaintiff by virtue of the

1 California survival statute, CA Code of Civ. Proc., §377.20.

2 **SECOND CLAIM FOR RELIEF**

3 **NEGLIGENCE PER SE (SURVIVAL ACTION)**

4 130. Plaintiff incorporates by reference all previous paragraphs of this
5 Complaint as if fully set forth here and further allege as follows:

6 131. Defendants violated applicable federal statutes and regulations relating to
7 prescription drugs. Plaintiff's Decedent was a person whom these statutes and regulations were
8 meant to protect.

9 132. Defendants' violation of these statutes or regulations constitutes negligence
10 per se.

11 133. Defendants' violation of these statutes or regulations was the direct,
12 producing, proximate and legal cause of Plaintiff's Decedent's injuries and damages. As the
13 direct, producing and legal cause and result of the Defendants' negligence, Plaintiff's Decedent
14 was injured and incurred damages, including but not limited to permanent physical injuries,
15 medical and hospital expenses in the past, past disability, past loss of use of the body, and past
16 physical and mental pain and suffering.

17 134. Plaintiff is therefore entitled to damages in an amount to be proven at trial,
18 together with interest thereon and costs.

19 135. Defendants' conduct, as alleged above, was malicious, intentional and
20 outrageous and constituted willful and wanton disregard for the rights or safety of others. Such
21 conduct was directed specifically at Plaintiff and was such as warrants an award of punitive
22 damages.

23 136. The aforesaid cause of action has survived to the Plaintiff by virtue of the
24 California survival statute, CA Code of Civ. Proc., §377.20.

25 **THIRD CLAIM FOR RELIEF**

26 **FRAUDULENT OMISSION AND CONCEALMENT (SURVIVAL ACTION)**

27 137. Plaintiff incorporates by reference all previous paragraphs of this
28 Complaint as if fully set forth here and further allege as follows:

1 138. Defendants had a confidential and special relationship with Plaintiff's
2 Decedent due to (a) Defendants' vastly superior knowledge of the health and safety risks relating
3 to Factor VIII and Factor IX, (b) Defendants' sole and/or superior knowledge of their dangerous
4 and irresponsible plasma collection practices; and (c) Defendants' direct communications with the
5 hemophiliac community through newsletters that purported to accurately convey the risk of
6 AIDS. As a result, Defendants had an affirmative duty to fully and adequately warn the
7 hemophiliac community, including Plaintiff's Decedent and his physicians, of the true health and
8 safety risks related to the Factor VIII and Factor IX blood products and constituent plasma and a
9 duty to disclose their dangerous and irresponsible plasma collection practices. Independent of
10 any special relationship of confidence or trust, Defendants had a duty not to conceal the dangers
11 of the products to Plaintiff's Decedent and his physicians.

12 139. Misrepresentations made by the Defendants about the health and safety of
13 their factor concentrate products independently imposed a duty upon Defendants to fully and
14 accurately disclose to the hemophiliac community, including Plaintiff's Decedent and his
15 physicians, the true health and safety risks related to Factor VIII and Factor IX and its constituent
16 plasma and a duty to disclose their dangerous and irresponsible plasma collection practices.

17 140. In connection with their Factor VIII and Factor IX products, Defendants
18 fraudulently and intentionally concealed important and material health and safety product risk
19 information from Plaintiff's Decedent, the hemophiliac community, and treating physicians, all as
20 alleged in this Complaint.

21 141. Any of the following is sufficient to independently establish Defendants'
22 liability for fraudulent omission and/or concealment:

23 a. Defendants fraudulently concealed the health and safety hazards,
24 symptoms, constellation of symptoms, diseases and/or health problems associated with their
25 Factor VIII and Factor IX blood products and related plasma collection activities;

26 b. Defendants fraudulently concealed their practice of using unsuitable
27 plasma from unsuitable donors in the manufacture of Factor VIII and Factor IX blood products;

28 c. Defendants fraudulently concealed their practice of avoiding the

1 use of available technology to detect viruses in Defendants' blood products and the components
2 thereof;

3 d. Defendants fraudulently concealed their practice of avoiding the
4 use of available technology to destroy viruses in Defendants' blood products and the components
5 thereof;

6 e. Defendants fraudulently concealed information about the known
7 comparative risks and benefits of the use of Factor VIII and Factor IX and the relative benefits
8 and availability of alternate products and therapies.

9 f. Defendants knew that Plaintiff's Decedent, the hemophiliac
10 community, and his physicians would regard the matters Defendants concealed to be important in
11 determining their course of treatment, including their decision whether to use Factor VIII and/or
12 Factor IX.

13 142. As a direct and proximate result of Defendants' fraudulent concealment
14 and suppression of material health and safety risks relating to Factor VIII and Factor IX and of
15 Defendants' dangerous and irresponsible plasma collection practices, Plaintiff and the Decedent
16 suffered and will continue to suffer injury, harm and economic loss. As the direct, producing,
17 proximate and legal cause and result of the Defendants' fraudulent concealment and suppression
18 of material health and safety risks relating to Factor VIII and Factor IX and of Defendants'
19 dangerous and irresponsible plasma collection practices, Plaintiff has been injured and has
20 incurred damages, including but not limited to the death of her decedent, medical and hospital
21 expenses in the past, past disability, Decedent's past loss of use of the body, past physical and
22 mental pain and suffering, and Decedent's loss of the enjoyment of life.

23 143. Plaintiff is therefore entitled to damages in an amount to be proven at trial,
24 together with interest thereon and costs.

25 144. Defendants' conduct, as alleged above, was malicious, intentional and
26 outrageous and constituted willful and wanton disregard for the rights or safety of others. Such
27 conduct was directed specifically at Plaintiff's Decedent and was such as warrants an award of
28 punitive damages.

1 145. Plaintiff is informed and believes that Defendants utilize retention policies
2 that provide for scheduled destruction of documents and other items, which may result in the
3 knowing, negligent, or inadvertent destruction of documents, data, and materials relevant and
4 necessary to adjudication of this action, including, but not limited to, records identifying batch or
5 lot numbers of Defendants' products shipped to particular treatment facilities abroad, which may
6 facilitate product tracing. This risk warrants an order from this Court that such evidence
7 (including all documents, data compilations, and tangible things within the meaning of Rule 26 of
8 the Federal Rules of Civil Procedure) be preserved and maintained for use in these proceedings.

9 146. The aforesaid cause of action has survived to the Plaintiff by virtue of the
10 California survival statute, CA Code of Civ. Proc., §377.20.

11 **FOURTH CLAIM FOR RELIEF**

12 **BREACH OF IMPLIED WARRANTY (SURVIVAL ACTION)**

13 147. Plaintiff incorporates by reference all previous paragraphs of this
14 Complaint as if fully set forth here and further allege as follows:

15 148. Defendants' factor concentrate products were intentionally designed,
16 manufactured, promoted, distributed and sold to be introduced into the human body.

17 149. Defendants breached the implied warranties of merchantability and fitness
18 because Defendants' factor concentrate products cannot pass without objection in the trade, are
19 unsafe, are not merchantable, are unfit for their ordinary use when sold, and are not adequately
20 packaged and labeled.

21 150. The aforesaid cause of action has survived to the Plaintiff by virtue of the
22 California survival statute, CA Code of Civ. Proc., §377.20.

23 **FIFTH CLAIM FOR RELIEF**

24 **WRONGFUL DEATH**

25 151. Plaintiff incorporates by reference all previous paragraphs of this
26 Complaint as if fully set forth here and further allege as follows:

27 152. Defendants marketed their Factor VIII and/or Factor IX blood products to
28 and for the benefit of Plaintiff's Decedent, and knew or had reason to know of the defects in their

representative capacity, against all Defendants, jointly and severally, in an amount to be determined at trial;

161. For punitive and exemplary damages according to proof against all Defendants;

162. For an award of prejudgment interest, costs, disbursements and reasonable attorneys' fees;

163. For injunctive relief in the form of an order requiring Defendants to preserve all relevant documents; and

164. For such other and further relief as the Court deems equitable or appropriate under the circumstances.

Dated: August 27, 2007

LIEFF, CABRASER, HEIMANN & BERNSTEIN, LLP

By: 

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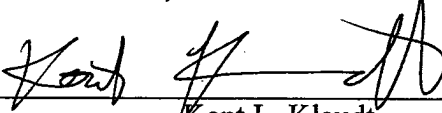
Attorneys for Plaintiff
LELIA INES BESSONE DE CASTRO

DEMAND FOR JURY TRIAL

COMES NOW PLAINTIFF LELIA INES BESSONE DE CASTRO and respectfully
demand that the present matter be set for a jury trial.

Dated: August 27, 2007

LIEFF, CABRASER, HEIMANN & BERNSTEIN, LLP

By: 
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